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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,222	06/04/2002	Hermanus Johannes Maria Kreuwel	9310-38	2628

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EXAMINER

LUDLOW, JAN M

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 08/26/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,222

Applicant(s)

KREUWEL ET AL.

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 are is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32,34-39,41 and 42 is/are allowed.
- 6) ☒ Claim(s) 1-31,33 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. Claim 32 is objected to because of the following informalities: In line 9, "second side of the third magnet array" appears to contain an error in that "the third magnet array" does not make sense with the preceding text. Appropriate correction is required.
2. Claims 17-21, 25, 27, 29, 31, 33, 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no teaching of moving the center set of magnets in a direction opposite of the first and third sets of magnets in the application as originally filed. There is no teaching with regard to dispersing clots formed prior to introduction into the containers. There is no teaching with respect to movement distance relative to magnet/container spacing. There is no teaching of moving containers along a continuous path.
3. The amendment filed June 19, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as explained above in the rejection.
4. Applicant is required to cancel the new matter in the reply to this Office Action.
5. Claims 1-6, 9-11, 13-15, 17-18, 22-24, 26, 28, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakazume in view of WO 96/26011 (Kirchanski et al).

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6. Sakazume teaches a method and apparatus for immunoassay by mixing magnetic particles in containers 1 using magnets 27 with like poles facing one another in an array, with a linear array of containers "intervening" (Figures 8 and 9). The containers are moved as shown by the arrows to provide a varying magnetic field (e.g., col. 2, lines 16-17). The system is "closed" in that the turntable provides a closed travel loop for the containers (col. 9, line 65). Alternatively, the system can be used with flow tubes (figure 10).

7. Sakazume fails to teach moving the magnets or nucleic acid isolation.

8. Kirchanski teaches a method and apparatus similar to that of Sakazume. Nucleic acids are taught as an alternative to antibodies in biospecific affinity reaction (p. 1, lines 8-24). Kirchanski further teaches that moving the magnets relative to a stationary container is an alternative to moving the containers relative to the magnets, see, e.g., Figures 1-4 and descriptions thereof.

9. It would have been obvious to one of ordinary skill in the art to configure the device of Sakazume to separate nucleic acids in a nucleic acid binding assay in order to test nucleic acids as an alternative to antibodies in a biospecific reaction as taught by Kirchanski. It would have been further obvious to move the magnets relative to the containers in order to provide an art recognized alternative to moving the containers past the magnets as taught by Kirchanski. With respect to claim 14, it would have been obvious to use conventional laboratory vessels, such as round bottom test tubes or microcentrifuge (Eppendorf) tubes for their known fluid containment purpose, such tubes having a smaller diameter at the bottom than at the top.

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10. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakazume as applied to claim 6 above, and further in view of Tuunanen and Komai et al.
11. Sakazume fails to teach a moveable heater.
12. Tuunanen teaches a magnetic particle immunoassay device. A heater is provided for controlled temperature incubation (col. 5, lines 27-28).
13. Tuunanen fails to teach a moveable heater for individual tubes.
14. Komai et al teaches a magnetic separation device. A moveable heater for encapsulating the bottom of a tube is used for temperature control (col. 9, lines 29-30).
15. It would have been obvious to use a temperature controller in Sakazume in order to incubate immunoassays at controlled temperature as taught by Tuunanen. It would have been obvious to provide the heater in the form of a moveable block with indentations in order to surround individual tubes and remove when not in use as taught by Komai.
16. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakazume as applied to claim 6 above, and further in view of Ammann et al and/or Howe et al.
17. Sakazume fails to teach means for moving the magnet in a vertical direction.
18. Ammann et al teach means for moving a magnet vertically to place it in, and remove it from, the position of use (Fig. 25).
19. Howe et al teach means for moving a magnet vertically to place it in, and remove it from, the position of use (Fig. 4A).

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20. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the magnets of Sakazume vertically moveable in order to remove them from engagement with the tubes when not in use as taught by Ammann et al and/or Howe et al.

21. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Komai et al in view of Sakazume, Kirchanski and Eddelmann.

22. Komai et al teach the method substantially as claimed, with the exception of the mixing method step (b) and moving the particles above the fluid step (l). See figure 10 and element 41.

23. The teachings of Sakazume are given above.

24. The teachings of Kirchanski are given above.

25. Eddelmann teaches lifting particles along the tube wall to remove from fluid to enhance separation (Figs. 7-12).

26. It would have been obvious to use the mixing method of Sakazume in the method of Komai in order to provide better mixing of magnetic particles in a fluid as taught by Sakazume. It would have been obvious to move the magnets instead of the tubes in order to achieve equivalent relative movement as taught by Kirchanski. It would have been further obvious to lift the particles above the fluid level using the magnet in order to provide better separation as taught by Eddelmann.

27. Claims 32, 34-39, 41-42 are allowed.

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28. The following is an examiner's statement of reasons for allowance: The prior art fails to teach or suggest the specific array geometry and movement. Note that Matte does not teach container between magnets, but rather above magnets.

29. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

30. Applicant's arguments filed June 19, 2003 have been fully considered but they are not persuasive.

31. Applicant argues that Sakazume forms clots, whereas the instant claims require mixing, but on page 3, lines 25-37, applicant has defined mixing as contacting the particles and fluid, and specifically recited that dispersion is not required for mixing as defined herein. Note also that figures 1-3 of the instant application show clumping of the particles during mixing. Applicant argues that the container oscillating embodiment of Sakazume teaches only single magnets on either side, not arrays, but figures 1 and 3 of the instant application show the use of single magnets (e.g., a 1x1 array), and claims 1 and 16 recite plural arrays of magnets, but does not require each array to have plural magnets.

32. Applicant argues that Kirchanski does not teach a starting particle that is a clot or aggregate, but the instant claims are not limited to breaking up clots. Applicant argues that Kirchanski does not teach a plurality of magnet arrays for mixing in a container array, but such is taught by Sakazume.

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33. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

34. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-

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4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

jml
August 25, 2003